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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/753,116

01/07/2004

Michael J. Kubek

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06/08/2006

LEYDIG VOIT & MAYER, LTD
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EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/753,116	Applicant(s) KUBEK, MICHAEL J.	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>01072004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

Receipt is acknowledged of the information disclosure statement filed 01/07/2004. While the US Patents and EPO reference could be retrieved, the non-patent literature references could not. Applicant is requested to forward copies of those references with the response to this action so that they may be considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for providing prolonged release of TRH hormone by stereotaxically implanting the non-spherical microstructures which are biodegradable into the central nervous system wherein the microstructures comprise 1-90% biodegradable polymer, and 1-60% TRH, does not reasonably provide enablement for generically providing TRH to the central nervous system. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification sets out these limitations at pages 3-4 (Summary of the Invention) as well as page 7, lines 21-24, and makes clear that they are required for the invention to function as claimed. Correction is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,360,610 (Tice et al) in view of EP 0 256 726 (EP'726).

Tice et al discloses a method of implanting microspheres directly into the central nervous system (see Abstract). The bioactive agents included are neurotransmitters, neuropeptides and neurotrophic factors (see col. 4, lines 44-50). Polymers used in the implanted microspheres are listed at claims 1, and 9-11. It should be noted that these are biodegradable. Tice et al differs from the instantly claimed invention in that TRH is not specifically disclosed for implantation into the central nervous system.

EP'726 discloses microencapsulated TRH (see Abstract and claims). EP'726 also uses some of the same polymers to construct their microencapsulated formulations (see claims 9-12). . Selection of a central locus is taught by the Tice reference, as well as implantation to such a central nervous site using the same biodegradable microstructures, while the specific TRH microstructures are taught by EP'726. Those of

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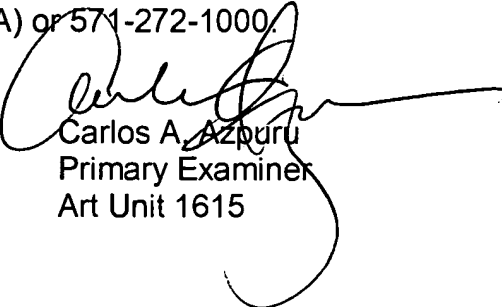
ordinary skill in the art would find it well within their skill to use the method of implanting biodegradable microparticles disclosed by Tice et al, and further to more specifically use microencapsulated TRH of EP'726 as one of the CNS implants with a reasonable expectation of beneficial results. While the references do not specifically recite the up regulation of glutamate and/or aspartate, they teach the implantation method using the instantly claimed microstructures. Since the same method of implanting the same microstructures of TRH is suggested by the combination of these references, one would expect similar physiological effects as a result. As such, those of ordinary skill would expect similar increases in the release of glutamate and/or aspartate as a result of the prolonged release of TRH from these microstructures within the central nervous system. There are no unusual and/or unexpected results which would rebut prima facie obviousness. The instant method of increasing glutamate and/or aspartate release in the central nervous system would have therefore been obvious given the teachings of Tice et al in view of EP'726.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Carlos A. Azpuru
Primary Examiner
Art Unit 1615

ca